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(12) # EUROPEAN PATENT SPECIFICATION

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(54) **Blood sampling unit.**

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Description

The invention relates to a blood sampling unit provided with a lancet for making a prick for blood, means for taking up blood and a holder suitable for containing a disinfectant, the holder, lancet and means comprises three separate components connected together such that in the storage and transport position they may be placed on top of each other in such a manner that the lancet is enclosed.

Such a unit is disclosed in FR—A—2 076 366. In the enclosed position of the lancet of this known unit this lancet is loose in the tube shaped holder, and the blood take-up tube is connected to a closing plug of said holder. After releasing said closing plug with the blood take-up tube, the loose lancet can be removed from the holder and can be used separately to make a prick for blood.

The blood sampling unit named in the introduction is characterized in that the lancet is mounted on one component and—in said enclosed state—projects through a recess or hole in another component.

The means for taking up blood can consist of a cuvette stored in a protective case or a small test plate which reacts with blood. In the storage and transport position the lancet has a well protected place inside said recess or hole. In the position for use the lancet has a fixed position on one of the components.

It is not precluded that the main components are mounted on top of each other by means of a snap-on system. It is much to be preferred, however, that hinges are used to join the main components to each other.

If the main components consist of plastic blocks, they can be manufactured cheaply in large numbers.

A very compact disposable unit which can in the main be manufactured in a single manufacturing step by injection moulding, comprises three plastic blocks joined together by narrow hinge strips, with the centre block having a blood take-up element in the form of a test strip and an opening for allowing the lancet through, which lancet is mounted on one of the other blocks in such a position that, when the blocks hinge on each other, the lancet is pushed fully through the opening until its sharp end projects in the working position.

In order that the hinge strips can be made very narrow, they are joined to the centre block at surfaces of the latter which are positioned opposite each other.

Both the small test strip and the disinfectant must be sealed from the atmosphere when the disposable unit is folded up. An easily removable means for this purpose is obtained if the block in which the holder for the disinfectant is kept and the centre block are covered by a common foil.

The user of the disposable unit will in general consider it an advantage if the unit includes a mechanism which can drive a needle through the skin of the finger at a relatively high speed. An extr mely simple mechanism for this purpose is characterised by a resistance which must be overcome by th lancet or th block on which the lancet is mounted, to allow the lancet to reach the operative final position with a certain speed.

It may happen that an attempt to pierce the skin of the finger to a sufficient extent miscarries. The block which contains the lancet must then be returned to the starting position. To facilitate this the block provided with the lancet may have one or more projecting parts, by means of which that block can be pushed back into the position in which the lancet or the block must overcome the resistance mentioned in order to be able to reach the operative final position. The projecting parts should also be able to fulfil a function in locking the two blocks.

In a further advanced construction the lancet is joined to a leaf spring which is held in the tensioned state as a result of the fact that a part of the lancet or spring is held back behind a stop of a block, which stop belongs to a part which can be tilted by exerting force into a position in which the lancet is driven rapidly into the operative position by the leaf spring.

After the blood has acted on the small test strip (time to take effect approx. 30—60 seconds), excess blood will have to be removed. The removal of this blood by absorption can take place in an extremely simple manner if in the storage and transport position in which it is folded up, the small test strip on the centre block is covered by a means of absorption on one of the other blocks. The means of absorption consists, for example, of an absorbing tissue.

The invention will now be explained in more detail by reference to the figures, in which a number of illustrative embodiments is shown.

Figure 1 shows a section of an initial embodiment of a blood sampling unit in which the components are in the storage position.

Figure 2 shows a section of this embodiment in the disinfecting position.

Figure 3 shows a section of this embodiment in the position for making a prick for blood and for taking up blood.

Figure 4 shows a plan view of Figure 1.

Figure 5 shows a section of a second embodiment of a blood sampling unit in which the components are in the storage position.

Figure 6 shows a section of a second embodiment with the components in the disinfecting position.

Figure 7 shows a section of the second embodiment in the position for making a prick for blood and taking up blood.

Figure 8 shows a plan view of Figure 7.

Figure 9 shows a section of a third embodiment with the components in the opened-out state.

Figure 10 shows a section of this third embodiment in the folded-up state.

Figure 11 shows a section of a fourth embodiment with a spring-tensioned drive mechanism for the lancet, the lancet being in the triggered position.

Figure 12 shows a section of the fourth embodiment in which the lancet is in the prick position.

The blood sampling unit according to Figures 1 to 4 inclusive comprises a small holder 1 containing disinfecting fluid, a cuvette 3 enclosed in a protective case 2, a lancet 4 mounted in the thickened edge of the protective case 2 and a small sealing cap 5 which in the storage position according to Figure 1 seals the inlet end of the cuvette. The small cap 5 has two recesses: a recess 7 for accommodating part of the small holder 1 and a recess 6 for accommodating the projecting part of the lancet 4.

The small holder 1, the small sealing cap 5 and the cuvette case 2 are joined together by a plastic strip 8. One of the advantages of this is that these components can be manufactured in a single working phase by injection moulding. Another advantage is that the parts 1, 2 and 5 remain together and after the unit has been used can be returned to the position according to Figure 1, in which the lancet 4 is enclosed.

The small holder 1 is sealed by a felt stopper 9. If this small holder is manufactured from a flexible material and its walls are pressed in, it should be possible to press out the disinfecting fluid through the felt. Another possibility is that the stopper is removed and is used like a pad of cotton wool.

The plastic strip 8 forms hinges in the assembled state of the unit. The strip 8 ends in an operating lip 11.

The unit is used as follows: first the small holder 1 is hinged from the position according to Figure 1 into the position according to Figure 2 and a part of the skin is smeared with disinfecting fluid. The strip 8 is then fully opened out and the situation according to Figure 3 arises. The exposed needle 4 is used to prick the sterile part of the skin and blood is deposited in the cuvette 3. The cuvette 3 is then removed from the case 2 and transferred to an analysis device. Because the cuvette 3 has been protected in the case 2 there will be no finger prints left behind on the cuvette 3 which might have affected the measurement.

The unit according to Figures 5—8 differs from the unit described in that the cuvette 3 with protective case 2 is replaced by a disc 12 with a small test strip 13 mounted on it which can react with a drop of blood and can then be placed in an analysis device. Usually, the analysis device is a glucometer which determines the blood sugar level, but other analyses are also possible.

The embodiment according to Figures 9 and 10 comprises three plastic blocks 14, 15 and 16 which are joined together by narrow hinge strips 17, 18 made of plastic material. The strips 17, 18 are joined to the centre block 15 at surfaces of the latter which are positioned opposite each other, and despite the narrow width of the hinge strips, th blocks can be folded up on top of each other as shown in Figure 10.

Block 14 is provided with recesses 19, 20 respectively intended for an absorbing element such as a tissue and for disinfectant.

In block 15 a hole 21 has been cut out which opens into a depression 22 designed to accept the top of a finger. Moreover a small test plate 23 which reacts with blood is fixed to the surface of block 15. The blocks 14 and 15 are sealed with an aluminium foil 24 which is provided with a tab 24a at one extremity.

A lancet 25 is mounted on the block 16, for example, by molding this lancet in during a single-step injection moulding of the unit 14, 15, 16.

The position of the lancet 25 is such that when the blocks 15 and 16 are folded together it is pushed through the hole 21. In the final position the point of the needle projects past the bottom of the depression 22 but just fails to reach the level of the surface of the block 15.

The block 16 is also provided with a depression 26 in which the top of a finger or the thumb can be placed.

Diagrammatically shown are locking elements 27, 28, by means of which the blocks 14, 16 are secured with respect to the block 15 in the state in which the unit is folded together. The locking elements 28 consist of two hooks placed on the side edges of the block 16 which can engage behind laterally projecting parts of the block 15.

The lancet 25 is mounted in a raised part 29 which can act together with a circumferential ring 21a which projects inwards in the hole 21 in such a way that the raised part encounters a resistance when the blocks 15 and 16 are pressed together and the lancet, after overcoming this resistance, is driven rapidly to its final position, at which a finger top placed on the depression 22 is pricked. The projecting parts 28 have, in addition to their locking function, still another function. If making the prick for blood miscarries, the block 16 must be returned to the starting position in which the resistance has to be overcome in order to allow the lancet to be able to reach the operative final position. This returning of block 16 to the starting position can be achieved through the parts 28 being pressed back by means of the block 14 until the position according to Figure 10 is reached.

It will be clear that the unit according to Figures 9 and 10 is used as follows: after the unit has been folded open and the foil 23 removed, a finger top is disinfected by means of the disinfectant contained in the holder 20. This finger top is then placed on the depression 22, after which the block 16 is folded onto the block 15 by means of a finger or thumb placed on the depression 26, as a result of which the lancet pricks the disinfected finger top. A drop of blood is transferred to the small test disc 23 which undergoes a discolouration in the course of approximately one minute as a result. Excess blood is removed by folding the block 14 against the block 15, as a result of which the absorption element, which, for example, consists of a tissue, in the recess 19 is brought into contact with the small test plate 23 and absorbs the blood. The degree of discolouration is a measure of the blood sugar level and this can be determined by means of a so-called glucometer

or coloured strip. After use the unit is thrown away.

The embodiment according to Figures 11 and 12 differs from those according to Figures 9 and 10 through the presence of a spring-loaded trigger mechanism for the lancet 25. For this purpose the lancet is joined to a leaf spring 31 which is provided with a projection 32 which in the triggered position is secured behind a tiltable part 33 of the block 16. As Figure 12 shows, by pressing the block 16 against the block 15 the part 33 will tilt, as a result of which the projection 32 of the leaf spring is no longer held back and the lancet is driven by the leaf spring at high speed to the position at which a finger top placed on the depression 22 is pricked.

Within the scope of the invention various modifications are possible. An essential feature of the invention is that the provisions which are necessary for the taking of blood samples are combined in a compact disposable unit, which unit consists of at least two, preferably three, parts or blocks, which in the storage and transport position are placed on top of each other in a manner such that the lancet is enclosed. The unit is not limited to determining the glucose level in the blood. Other blood samplings are also possible, for example for determining the cholesterol level, pregnancy and the like.

Claims

1. Blood sampling unit provided with a lancet (4; 25) for making a prick for blood, means (2; 23) for taking up blood and a holder (1; 20) suitable for containing a disinfectant, the holder, lancet and means comprises three separate components (1, 5, 2, 3; 1, 5, 12; 14, 15, 16) connected together such that in the storage and transport position they may be placed on top of each other in such a manner that the lancet is enclosed, characterized in, that the lancet (4; 25) is mounted on one)component (2; 16) and — in said enclosed state — projects through a recess or hole (6; 21) in another component (5; 15).

2. Blood sampling unit according to claim 1, characterized in, that the components are jointed by hinges (8; 17, 18).

3. Blood sampling unit according to one of the foregoing claims, characterized in, that the components consist of plastic blocks (14, 15, 16).

4. Blood sampling unit according to claim 3, characterized in, that the throw-away unit comprises three plastic blocks (14, 15, 16) which are joined together by narrow hinge strips (17, 18), that the centre block (15) has a blood take-up element (23) in the form of a test strip and an opening (21) for allowing the lancet (25) through, which lancet is mounted on one (16) of the other blocks in such a position that, when the blocks (15, 16) hinge on each other, the lancet is pushed fully through the opening until its sharp end projects in the working position.

5. Blood sampling unit according to claim 4, characterized in, that the two hinge strips (17, 18) are joined to the centre block (15) at surfaces of the latter which are positioned opposite each other.

6. Blood sampling unit according to claim 4 or 5, characterized in, that the block (14) in which the holder (20) for the disinfectant is kept and the centre block (15) are covered by a common foil (29).

7. Blood sampling unit according to one of the foregoing claims, characterized by a resistance which must be overcome by the lancet (25) or the block (16) on which the lancet is mounted, to allow the lancet to reach the operative final position with a certain speed.

8. Blood sampling unit according to claim 7, characterized in, that the block (16) provided with the lancet (25) has one or more projecting parts (28), by means of which that block can be pushed back into the position in which the lancet (25) or the block (16) must overcome the resistance mentioned in order to be able to reach the operative final position.

9. Blood sampling unit according to one of claims 4, 5 or 6, characterized in that the lancet (25) is joined to a leaf spring (31) which is held in the tensioned state as a result of the fact that a part (32) of the lancet or spring is held back behind a stop of a block, which stop belongs to a part (33) which can be tilted by exerting force into a position in which the lancet is driven rapidly into the operative position by the leaf spring.

10. Blood sampling unit according to one of claims 5—9, characterized in that in the storage and transport position in which it is folded up, the test strip (23) on the centre block (15) is covered by a means of absorption (19) on one of the other blocks (14).

Patentansprüche

1. Blutprobeneinheit mit einer Lanzette (4; 25) zur Herstellung eines Einstichs für Blut, einer Einrichtung (2; 23) zur Aufnahme von Blut und einem Halter (1; 20), der zur Aufnahme eines Desinfektionsmittels geeignet ist, wobei der Halter, die Lanzette und die Einrichtung drei getrennte Komponenten (1, 5, 2, 3; 5, 12; 14, 15, 16) umfassen, die miteinander so verbunden sind, daß sie in der Lager- und Transportposition derart übereinander angeordnet werden können, daß die Lanzette eingeschlossen ist, dadurch gekennzeichnet, daß die Lanzette (4; 15) an einer der Komponenten (2; 16) angebracht ist und in der eingeschlossenen Stellung durch eine Ausnehmung oder eine Loch (6; 21) in einer anderen Komponente (5; 15) hindurchragt.

2. Blutprobeneinheit nach Anspruch 1, dadurch gekennzeichnet, daß die Komponenten durch Scharniere (8; 17, 18) verbunden sind.

3. Blutprobeneinheit nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Komponenten aus Kunststoffblöcken (14, 15, 16) bestehen.

4. Blutprobeneinheit nach Anspruch 3, dadurch gekennzeichnet, daß die Wegwerf-Einheit drei

Kunststoffblöcke (14, 15, 16) umfaßt, die miteinander durch schmale Scharnierbänder (17, 18) verbunden sind, daß der mittlere Block (15) ein Blutaufnahme-Element (23) in der Form eines Teststreifens und eine Öffnung (21), die ein Eintreten der Lanzette (25) gestattet, umfaßt, welche Lanzette an einem (16) der anderen Blöcke in einer derartigen Position angebracht ist, daß, wenn die Blöcke (15, 16) zusammengeklappt sind, die Lanzette vollständig durch die Öffnung hindurchtritt, bis ihr scharfes Ende in die Arbeitsposition herausragt.

5. Blutprobeneinheit nach Anspruch 4, dadurch gekennzeichnet, daß die beiden Scharnierbänder (17, 18) mit dem mittleren Block (15) an dessen Oberflächen verbunden sind, die einander gegenüberliegen.

6. Blutprobeneinheit nach Anspruch 4 oder 5, dadurch gekennzeichnet, daß der Block (14), in dem sich der Halter (20) für das Desinfektionsmittel befindet, und der mittlere Block (15) durch eine gemeinsame Folie (29) abgedeckt sind.

7. Blutprobeneinheit nach einem der vorhergehenden Ansprüche gekennzeichnet durch einen Widerstand, der durch die Lanzette (25) oder den Block (16), auf dem sich die Lanzette befindet, überwunden werden muß, damit die Lanzette die endgültige Gebrauchsstellung mit einer gewissen Geschwindigkeit erreicht.

8. Blutprobeneinheit nach Anspruch 7, dadurch gekennzeichnet, daß der Block (16), der mit der Lanzette (25) versehen ist, einen oder mehrere vorspringende Teile (18) aufweist, mit deren Hilfe der Block zurückgedrückt werden kann in die Position, in der die Lanzette (25) oder der Block (16) den Widerstand überwinden muß, damit die endgültige Gebrauchsposition erreicht wird.

9. Blutprobeneinheit nach einem der Ansprüche 4, 5 oder 6, dadurch gekennzeichnet, daß die Lanzette (25) mit einer Blattfeder (31) verbunden ist, die in gespannter Stellung gehalten wird als Ergebnis der Tatsache, daß ein Teil (32) der Lanzette oder Blattfeder hinter einem Anschlag eines Blockes zurückgehalten wird, welcher Anschlag zu einem Teil (33) gehört, der durch Ausübung einer Kraft in eine Position gekippt werden kann, in der die Lanzette durch die Blattfeder rasch in die Gebrauchsposition bewegt wird.

10. Blutprobeneinheit nach einem der Ansprüche 5 bis 9, dadurch gekennzeichnet, daß in der Lager- und Transportposition, in der die Einheit zusammengefaltet ist, der Teststreifen (23) des mittleren Blocks (15) durch eine Absorptionseinrichtung (19) auf einem der anderen Blöcke (14) abgedeckt ist.

Revendications

1. Unité de prélèvement de sang munie d'une lancette (4; 25) pour effectuer une prise de sang, des moyens (2; 23) pour recueillir le sang, et un réceptacle (1; 20) apte à contenir un désinfectant, le réceptacle, la lancette et les moyens constituant trois éléments séparés (1, 5, 2, 3; 1, 5, 15; 14, 15, 16) reliés ensemble de manière que dans la position de stockage et de transport ils puissent être placés les uns au-dessus des autre de façon que la lancette soit enfermée, caractérisée en ce que la lancette (4; 25) est montée sur un élément (2; 16) et—dans l dit étant enfermé—fait saillie dans un évidement ou un trou (6; 21) constitué dans un autre élément (5; 15).

2. Unité de prélèvement de sang selon la revendication 1, caractérisée en ce que les éléments sont reliés par des charnières (8; 17, 18).

3. Unité de prélèvement de sang selon l'une des revendications précédentes, caractérisée en ce que les éléments consistent en des blocs en matière plastique (14, 15, 16).

4. Unité de prélèvement de sang selon la revendication 3, caractérisée en ce que l'unité jetable comprend trois blocs en matière plastique (14, 15, 16) qui sont reliés les uns aux autres par d'étroites bandes formant charnières (17, 18), en ce que le bloc central comprend un élément pour recueillir le sang (23) ayant la forme d'une bande réactive et une ouverture (21) pour permettre le passage de la lancette (25), cette lancette étant montée sur l'un (16) des autres blocs dans une position telle que lorsque les blocs (15, 16) sont repliés l'un sur l'autre la lancette est poussée en totalité dans l'ouverture jusqu'à ce que son extrémité pointue fasse saillie dans la position de travail.

5. Unité de prélèvement de sang selon la revendication 4, caractérisée en ce que les deux bandes formant charnières (17, 18) sont reliées au bloc central (15) sur les surfaces de ce dernier qui sont à l'oppose l'une de l'autre.

6. Unité de prélèvement de sang selon la revendication 4 ou 5, caractérisée en ce que le bloc (14) dans lequel est prévu le réceptacle (20) destiné au désinfectant et le bloc central (15) sont recouverts par une feuille commune (29).

7. Unité de prélèvement de sang selon l'une des revendications précédentes, caractérisée par une résistance qui doit être surmontée par la lancette (25) ou le bloc (16) sur lequel la lancette est montée pour permettre à la lancette d'atteindre sa position de fonctionnement finale avec une certaine vitesse.

8. Unité de prélèvement de sang selon la revendication 7, caractérisée en ce que le bloc (16) qui est muni de la lancette (25) comprend une ou plusieurs parties en saillie (28) au moyen desquelles ce bloc peut être repoussé dans la position dans laquelle la lancette (25) ou le bloc (16) doit surmonter la résistance mentionnée de façon à pouvoir atteindre la position de fonctionnement finale.

9. Unité de prélèvement de sang selon l'une des revendications 4, 5 ou 6, caractérisée en ce que la lancette (25) est reliée à un ressort à lame (31) qui est maintenu sous tension du fait qu'une partie (32) de la lancette ou du ressort est retenue à l'arrière d'une butée d'un bloc, cette butée appartenant à une partie (33) qui peut être basculée par l'application d'une force dans une position dans laquelle la lancette est rapidement amenée à sa position de fonctionnement par le ressort à lame.

10. Unité de prélèvement de sang selon l'une des revendications 5—9, caractérisée en ce que dans la position de stockage et de transport dans laquelle ell est repliée, la bande réactive (23) du bloc central (15) est recouverte par un moyen d'absorption (19) sur l'un (14) des autres blocs.

fig-2

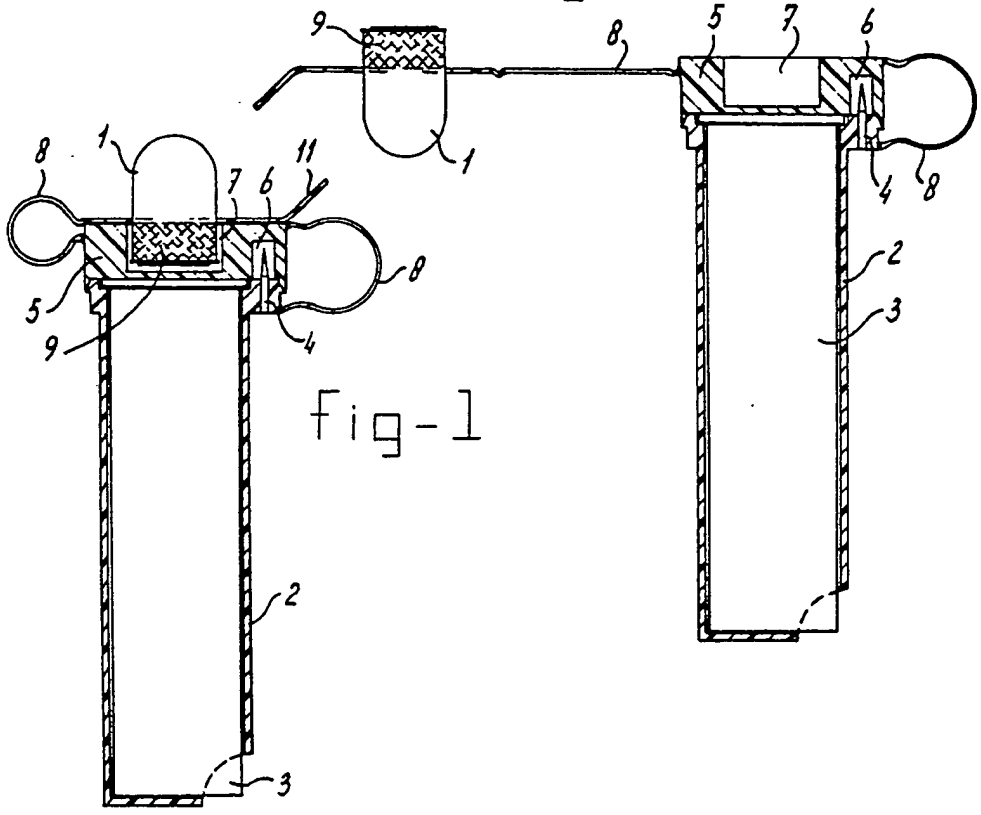


fig-1

fig-3

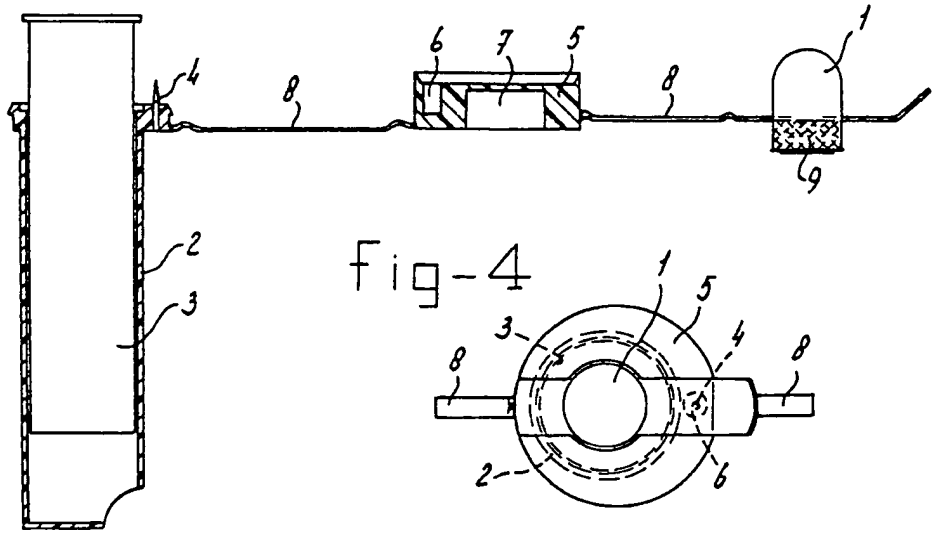


fig-4

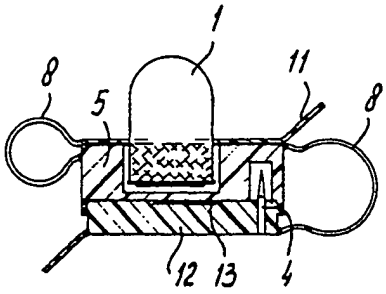
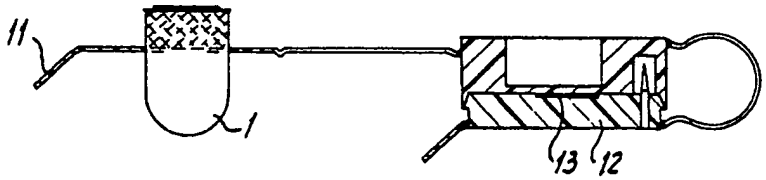


Fig-5

Fig-6



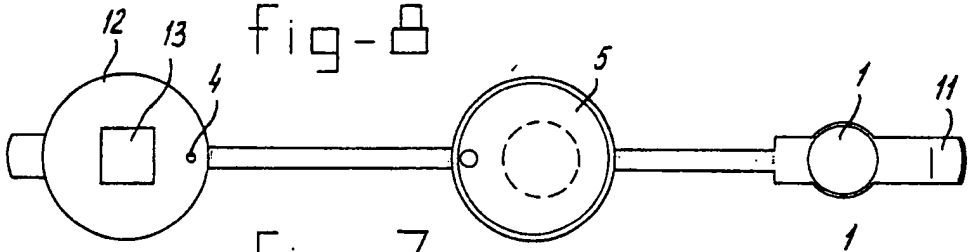


Fig-8

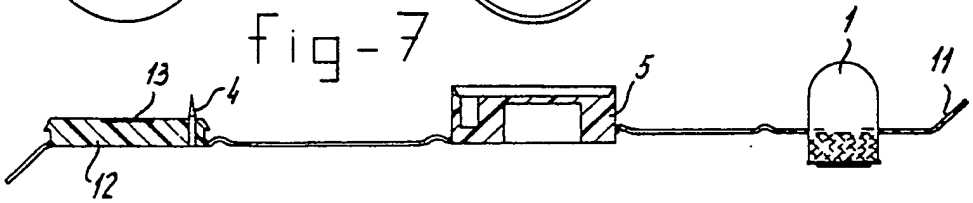


Fig-7

fig - 9

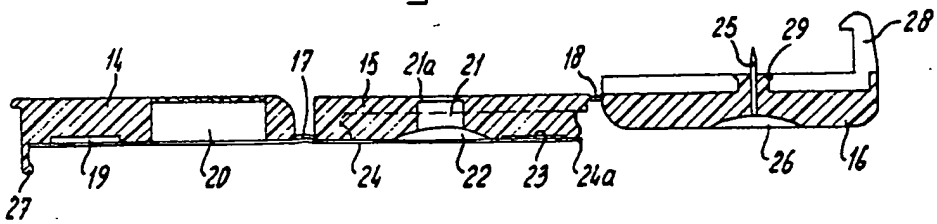


fig - 10

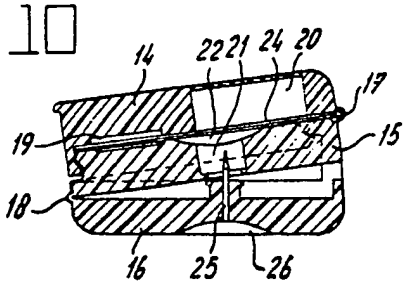


fig - 11

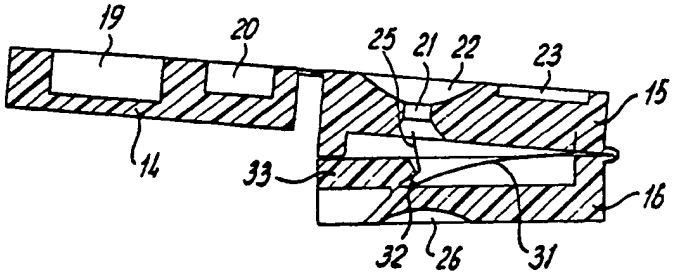


fig - 12